K022666

ARC Medical Supplies(Beijing) Co., Ltd.

OCT 0 9 2002

#66 Qian Ban Bi Jie, Xizhimen Nei,
Beijing CHINA 100035
Tel: 8610-6617 8581 Fax: 8610-66113481
Email: arcmedic@public.bta.net.cn

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: _____.

Applicant	ARC Medical Supplies (Beijing) Co., Ltd. #66 Quian Ban Bi Jie, Xizhimen Nei Beijing, China 100035 Telephone: 8610 6617 8581 Fax: 8610 6611 3481
Contact Person	Mr. Charles F. Andrews C.F. Andrews & Associates 1591 S. Moorland Road, Suite 104 New Berlin, WI 53151 Telephone: (414) 416-9119 Fax: (414) 389-1650
Date	August 7, 2002
Name of Device	
Proprietary Name:	PDO (Polydioxanone) Monofilament Synthetic Absorbable Suture U.S.P.
Common or Usual Name:	Polydioxanone Monofilament Synthetic Absorbable Suture U.S.P.
Classification Name:	Suture, Absorbable, Synthetic, Polydioxanone

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510(k) SUMMARY - continued

PDO (Polydioxanone) Monofilament Synthetic Absorbable Sutures, U.S.P. manufactured by ARC Medical Supplies (Beijing) Co., Ltd. are equivilent to MONO-DOX synthetic absorbable polydioxanone surgical sutures manufactured by CP Medical.

The PDO (Polydioxanone) Monofilament Synthetic Absorbable Sutures, U.S.P. manufactured by ARC Medical and CP Medical are monofilament suture composed of a Poly(p-dioxanone) acid, un-dyed or dyed with D&C Violet No. 2.

PDO (Polydioxanone) Monofilament Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDO is not indicated for use in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are useful where an absorbable suture with extended wound support (up to six weeks) is desirable.

Testing of suture diameter, suture length, knot pull tensile strength, needle attachment strength and absorption rate according to methods outlined in U.S.P. XXIII demonstrates that ARC Medical PDO (Polydioxanone) Monofilament Synthetic Absorbable sutures meet or exceed U.S.P. specifications and are equivalent in terms of the above parameters to Synthetic Absorbable polydioxanone surgical sutures manufactured by CP Medical.

Richard Kuo, Chairman

8-6-02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ARC Medical Supplies (Beijing) Co., Ltd.
c/o Mr. Charles F. Andrews
President
C.F. Andrews & Associates
1591 S. Moorland Road, Suite 104
New Berlin, Wisconsin 53151

OCT 0 9 2002

Re: K022666
Trade/Device Name: PDO (Polydioxanone) Monofilament Synthetic Absorbable Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Suture, surgical, absorbable, polydioxanone
Regulatory Class: Class II
Product Code: NEW
Dated: August 29, 2002
Received: August 30, 2002

Dear Mr. Andrews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

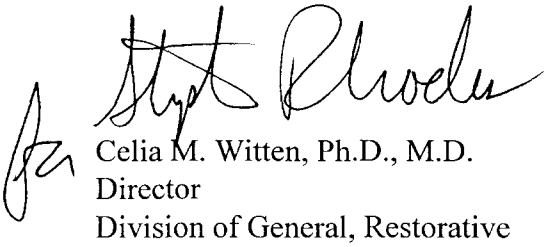
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022666

510(k) Number : K022666

Device Name: **PDO (Polydioxanone) Monofilament Synthetic Absorbable Suture U.S.P.**

Indications for Use: **PDO (Polydioxanone) Monofilament Synthetic Absorbable Sutures U.S.P. are indicated for use in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDO is not indicated for use in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are useful where an absorbable suture with extended wound support (up to six weeks) is desirable.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022666